JUL 2 4 2000

510(K) SUMMARY
(as required by 807.92 9c))

K000350

Submitter of 510(K): Regulatory & Marketing Service, Inc. (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Phone: 727-376-4154
Fax: 727-376-7186

Contact Person: Art Ward

Date of Summary: 2/11/00

Trade Name: The Zurich Pediatric Maxillary Distractor

Classification Name: Distractor

Predicate Device: K982604
Lorenz Maxilla (Le Fort) Distraction System
Walter Lorenz Surgical, Inc.

Device Description/
Comparison:

KLS-Martin, L.P. manufactures Distraction Osteogenisis Devices for use in the maxillofacial skeletal system. Osteodistraction is a technique of bone lengthening which utilizes the body's natural healing mechanisms to generate new bone. An osteotomy or corticotomy is made in the selected skeletal area in which the distraction device is to be placed. Upon activation, the distraction device slowly elongates the bone to its new dimension while ossification produces new bone at the site of distraction. The Zurich Distractor is the same as the predicate device except being made from a different Titanium Alloy

Intended Use: The Zurich Pediatric Maxillary Distractor is intended for use in the maxilla as a bone stabilizer and lengthening device when correction of congenital mid facial deficiencies or posttraumatic defects require gradual bone distraction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2000

KLS-Martin L.P.
C/O Mr. Arthur J. Ward
Regulatory & Marketing Services, Incorporated (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Re: K000580
Trade Name: Zurich Pediatric Maxillary Distractor, Models 51-550-15 and 51-551-15
Regulatory Class: II
Product Code: MQN
Dated: May 24, 2000
Received: May 31, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000580

Device Name: Zurich Pediatric Maxillary Distractor

Indications For Use:

The Zurich Pediatric Maxillary Distractor is intended for use in the maxilla as a bone stabilizer and lengthening device when correction of congenital mid facial deficiencies or posttraumatic defects require gradual bone distraction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000580